

ORIGINAL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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91095

McNEIL-PPC, INC., :

Plaintiff, :

OPINION

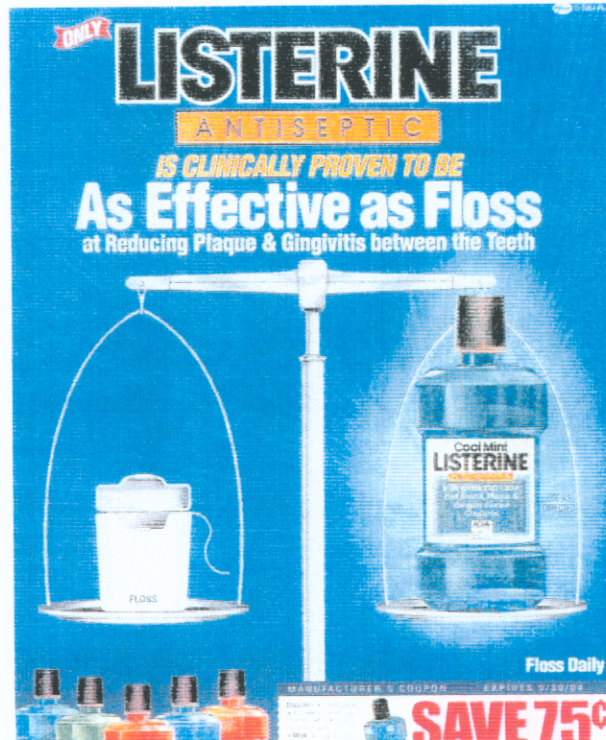
- against - :

04 Civ. 7684 (DC)

PFIZER INC., :

Defendant. :

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FILED OPINION
U.S. DISTRICT COURT
2005 JAN -6 P 4:16
SOUTHERN DISTRICT
OF NEW YORK

CHIN, D.J.

In June 2004, defendant Pfizer Inc. ("Pfizer") launched a consumer advertising campaign for its mouthwash, Listerine Antiseptic Mouthrinse. Print ads and hang tags featured an image of a Listerine bottle balanced on a scale against a white container of dental floss, as shown above.

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The campaign also featured a television commercial called the "Big Bang." In its third version, which is still running, the commercial announces that "Listerine's as effective as floss at fighting plaque and gingivitis. Clinical studies prove it." Although the commercial cautions that "[t]here's no replacement for flossing," the commercial repeats two more times the message that Listerine is "as effective as flossing against plaque and gingivitis." The commercial also shows a narrow stream of blue liquid flowing out of a Cool Mint Listerine bottle, then tracking a piece of dental floss being pulled from a white floss container, and then swirling around and between teeth -- bringing to mind an image of liquid floss.

In this case, plaintiff McNeil-PPC, Inc. ("PPC"), the market leader in sales of string dental floss and other interdental cleaning products, alleges that Pfizer has engaged in false advertising in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and unfair competition in violation of state law. PPC contends that Pfizer's advertisements are false and misleading in two respects. First, PPC contends that Pfizer's literal (or explicit) claim that "[c]linical studies prove" that Listerine is "as effective as floss against plaque and gingivitis" is false. Second, PPC contends that Pfizer's advertisements also implicitly are claiming that Listerine is a replacement for floss -- that all the benefits of flossing may be obtained by rinsing with Listerine -- and that this implied message is false and misleading as well.

Before the Court is PPC's motion for a preliminary injunction enjoining Pfizer from continuing to make these claims in its advertisements. For the reasons set forth below, I conclude that Pfizer's advertisements are false and misleading. PPC's motion is granted and a preliminary injunction will be issued. My findings of fact and conclusions of law follow.

STATEMENT OF THE CASE

A. The Facts

1. The Parties and Their Products

PPC, a wholly-owned subsidiary of Johnson & Johnson ("J&J"), manufactures and markets consumer oral health products. PPC is the market leader in the sales of interdental cleaning products (Tr. 286-87, 292-93),¹ including dental floss -- waxed or unwaxed string used to mechanically remove food and debris from between the teeth and underneath the gumline. (See, e.g., DX 131). According to the label on J&J's Reach dental floss:

Dentists recommend regular flossing.
Flossing has been clinically proven to remove
plaque between teeth to help prevent gum
disease.

(Id.). The label states that "Flossing is easy with the proper technique." It instructs users to "[g]ently slide floss between

References to "Tr." are page references to the transcript of the preliminary injunction hearing. References to "PX" and "DX" are to plaintiff's exhibits and defendant's exhibits, respectively, received into evidence at the hearing. The vast majority of the exhibits were received without objection and were marked both as plaintiff's exhibits and as defendant's exhibits. For convenience, where an exhibit was marked with two numbers, I use the PX number in most instances.

teeth" and "[m]ove floss up and down against tooth to clean both above and below the gum line, curving the floss around the tooth for best results." (Id.). The procedure is to be repeated for each tooth. (Id.).

J&J invented floss nearly 100 years ago. (See Tr. 286). PPC's products include the Reach Access Daily Flosser (the "RADF"), a toothbrush-like device with a snap-on head (to be replaced after each use) containing a piece of string floss. (PX 172). The RADF was launched in August 2003. PPC also sells a battery-powered version of the RADF, called the Reach Access Power Flosser. (PX 173).

Pfizer manufactures and markets consumer and pharmaceutical products, including Listerine, an essential oil-containing antimicrobial mouthrinse. (See, e.g., PX 162 (Cool Mint Listerine)). According to its label, Listerine:

Kills germs that cause Bad Breath, Plaque & the gum disease Gingivitis.

(Id.). Listerine has been "accepted" by the American Dental Association (the "ADA") and bears the ADA seal of acceptance on its label. (Id.). The label instructs users to rinse with Listerine full strength for 30 seconds, each morning and night. (Id.). Listerine also comes in several flavors, including Cool Mint, Fresh Burst, and Natural Citrus.

2. Oral Hygiene and Oral Diseases

Plaque is a biofilm comprised of a thin layer of bacteria that forms on teeth and other surfaces of the mouth.

Food debris caught between teeth provides a source of nutrition for this bacteria and will help the bacteria multiply, grow, and persist. Plaque build-up may cause gingivitis, an inflammation of the superficial gum tissues surrounding the tooth. Gingivitis is common, affecting some two-thirds of the U.S. population. Its symptoms include red, inflamed, swollen, puffy, or bleeding gums. Periodontitis is inflammation that develops in deeper tissues, and involves the bone and connection to the tooth (the periodontal ligament). Periodontitis is less common, affecting some 10-15% (more or less) of the population, although it becomes more prevalent with age. It is a major cause of tooth loss. (Tr. 152-54, 160, 166; PXs 25, 56, 57, 178, 205 at 454; DX 408 at 100003039).

Gingivitis is generally considered an early form of or precursor to periodontitis. (Tr. 152, 194; see, e.g., PX 228 at 1 ("gingival inflammation is thought to be a prerequisite to the development of periodontitis")). The ADA refers to mild or moderate gingivitis as "early gum disease" and periodontitis as "advanced gum disease." (PX 51). Gingivitis does not always progress to periodontitis, but "it is rare for periodontitis not to be preceded by gingivitis." (PX 213 at 16192; see Tr. 361).

The removal of plaque and the prevention of plaque build-up are critical to addressing both gingivitis and periodontitis. (Tr. 154, 166).² In addition, although it is

² Pfizer's expert, Dr. Hujoel, suggested in his testimony that there is no connection between plaque and periodontitis. (See Tr. 349-51). I am not persuaded by his testimony and I

less clear, controlling plaque also helps prevent or reduce "caries" -- cavities or dental decay. (Tr. 146, 153-54, 165-67).³ The ADA recognizes that "[p]laque is responsible for both

reject it. (See also PX 57 at 354 ("It has been well established that periodontal diseases can be controlled by thorough plaque control."); PX 205 at 449 ("maintenance of a high status of oral cleanliness prevents or reduces the progression of periodontitis"); PX 209 at 186 (clinical trial that included program of improved self-performed tooth cleaning showed over 15-year period low incidence of caries and periodontal disease); PX 210 at 171 ("frequent removal of plaque or the prevention of its formation may be considered effective methods for the prevention of the two most prevalent oral diseases" -- periodontal disease and dental caries); PX 225 at 134 (noting studies demonstrate "effectiveness of mechanical plaque control in the prevention of gingivitis and periodontal disease progression"); PX 223 at 300 ("role of dental plaque as the primary aetiological factor in chronic inflammatory periodontal disease" is generally accepted)). Even Pfizer, on its own website, acknowledges that "flossing is essential in preventing gum disease." (PX 41 at 090636).

³ Again, Pfizer's expert, Dr. Hujoel, seemed to suggest that the removal of plaque by personal oral hygiene procedures would have no effect on tooth decay. (Tr. 352). I also reject this suggestion. (See PX 208 at 3 ("Recent studies have shown conclusively that dental caries in children can be almost completely prevented by the efficient removal of dental plaque."); PX 210 at 171 ("The presence of dental plaque on the teeth and oral tissues is recognized as being a requirement for the initiation of (both) periodontal disease and dental caries." (footnotes omitted)); PX 216 at 65 ("presence of plaque has the potential to lead to gingivitis and periodontal disease, as well as interproximal caries"); PX 224 at 574 ("[i]nterdental plaque has been implicated as the causative agent" of certain dental caries); PX 225 at 147 ("maintenance of proper plaque control procedures is also effective in preventing caries from developing"); PX 228 at 2 (study showed decline in incidence of approximal caries following three years of improved oral hygiene training program)).

The approximal (or proximal) areas are the visible spaces between teeth that are not below the area where two teeth come into contact. The interproximal (or interdental) areas are the areas under the point of contact and the contact area itself. (PX 205 at 454; Tr. 152). "Subgingivally" refers to below the gum line. (Tr. 151).

tooth decay and gum disease." (PX 51).

The most common method of mechanically removing plaque is brushing, and today the use of toothbrushes and fluoridated toothpastes is "almost universal." (PX 205 at 450; see also PX 56 at 360 ("close to 100 percent . . . reported daily toothbrushing"))⁴ Brushing, however, does not adequately remove plaque. In part, this is because many people do not brush properly or they brush less than the recommended two minutes twice a day. (PX 205 at 450). In part, it is also because for most people "toothbrushing alone cannot effectively control interproximal plaque," i.e., the plaque in the hard-to-reach places between the teeth. (Id. at 454). As a consequence, removal of plaque from the interproximal areas by additional methods is particularly important, for it is in these areas between the teeth that plaque deposits appear early and become more prevalent. (PX 205 at 454). The direct interproximal area is the area where there is "the most stagnation" and where "periodontal disease usually starts." (Tr. 193).

Traditionally, the "most widely recommended" mechanical device for removing interproximal plaque is dental floss. (PX 56 at 360; see also PX 57 at 352; PX 205 at 454 ("Of all the methods for removing interproximal plaque, flossing is the most universal."); PX 214 at 876 ("Dental floss is still the most

⁴ Procedures for removing plaque "are as old as recorded history," as it is reported that "Hippocrates (460-377 BC) included in his writings commentaries on the importance of removing deposits from the tooth surfaces." (PX 205 at 450).

effective means we have to date for removing subgingival interproximal dental plaque."); Tr. 580 ("the gold standard"); Kumar Dep. 43 ("Brushing and flossing are standards for plaque control.")). The ADA recommends "brushing twice a day and cleaning between the teeth with floss or interdental cleaners once each day to remove plaque from all tooth surfaces." (PX 51). Flossing provides a number of benefits. It removes food debris and plaque interdentally and it also removes plaque subgingivally. As part of a regular oral hygiene program, flossing helps reduce and prevent not only gingivitis but also periodontitis and caries. (Tr. 151-52; see also Kumar Dep. 22; authorities cited in footnotes 2 and 3 supra).⁵

Some 87% of consumers, however, floss either infrequently or not at all. (Tr. 289). Although dentists and dental hygienists regularly tell their patients to floss (Tr. 289),⁶ many consumers do not floss or rarely floss because it is

⁵ Pfizer's position in this case is that while flossing does reduce plaque and gingivitis, there is no credible evidence that it reduces periodontitis or tooth decay. (Tr. 349, 352-58, 360-61). In fact, Pfizer argues that rinsing with Listerine provides all the benefits of flossing (Tr. 373-74 ("Flossing does not provide any health benefit" not provided by Listerine.); see also Tr. 450) and flatly declares that the "widely-held belief that floss does something further than treat plaque and gingivitis . . . is a myth." (Tr. 16). I reject the argument.

⁶ Pfizer's expert witnesses implicitly acknowledged that this is the case. Although asked by the Court three times, Dr. Hujoel refused to answer the question whether he has been telling his patients for ten years to floss. (Tr. 353-54). Dr. Garcia more frankly acknowledged that he, his wife, and two children are "flossers," and suggested they would continue to floss. (Tr. 460).

a difficult and time-consuming process. (Tr. 289; see Schorr Dep. 129).⁷

As a consequence, a large consumer market exists to be tapped. If the 87% of consumers who never or rarely floss can be persuaded to floss more regularly, sales of floss would increase dramatically. PPC has endeavored, with products such as the RADF and the Power Flosser, to reach these consumers by trying to make flossing easier. (Tr. 289).

At the same time, Pfizer has recognized that there is enormous potential here for greater sales of Listerine as well. Pfizer has come to realize that if it could convince consumers who were reluctant flossers that they could obtain the benefits of flossing by rinsing with Listerine, it would be in a position to see its sales of Listerine increase dramatically. (See Schorr Dep. 129 (Pfizer's associate product manager for Listerine agreeing that Pfizer's "as effective as floss" campaign is targeted towards people who do not floss or do not regularly floss because "[t]hey are consumers, and we want them to buy Listerine"))).

In the context of this case, therefore, Pfizer and PPC are competitors. (Tr. 291-92; PX 145; but see Tr. 667-68).

⁷ "For some individuals [flossing] is not easy to perform, especially in posterior areas, since it requires manual dexterity, is time-consuming, there is a risk of frequent shredding when passing through the contact point and there is risk of tissue damage if improperly used." (PX 205 at 455; see also PX 56 at 360 ("[P]atients' requisite ability and motivation to thoroughly floss sites throughout the entire mouth once daily often is lacking, leading to frustration on the part of dental professionals and patients alike.")).

3. The Listerine Studies

Pfizer sponsored two clinical studies involving Listerine and floss: the "Sharma Study" and the "Bauroth Study." (See PXs 56, 57). These studies purported to compare the efficacy of Listerine against dental floss in controlling plaque and gingivitis in subjects with mild to moderate gingivitis.

a. The Sharma Study

The Sharma Study resulted in an article entitled "Comparative effectiveness of an essential oil mouthrinse and dental floss in controlling interproximal gingivitis and plaque," published in the American Journal of Dentistry in December 2002. 15 Am. J. Dentistry 351 (2002) (PX 57). The Sharma study used 319 subjects, aged 18-63, who had mild to moderate gingivitis and dental plaque. (PX 57 at 352; PX 58 at 51907-08). The subjects were randomly placed into one of three groups, with each group following a different regimen: (i) daily toothbrushing plus rinsing with original Listerine Antiseptic mouthrinse twice a day (the "Listerine group"); (ii) daily toothbrushing plus flossing once a day (the "flossing group"); and (iii) daily toothbrushing plus rinsing with a placebo control rinse twice a day (the "control group"). (PX 57 at 352; PX 58 51908-11). At the outset, all subjects received baseline examinations and received scores for baseline levels of plaque and gingivitis, measured by three indices. (PX 57 at 352). Following these baseline examinations, all subjects received a complete dental prophylaxis to remove plaque, stain, and calculus. (Id.).

The subjects then were started on their assigned regimen. The first rinsing or flossing was performed with instruction and supervision. Rinse subjects rinsed with 20 ml for 30 seconds and were provided with a supply of coded mouthrinse and plastic dosage cups for twice-daily use. Floss subjects received flossing instruction from a dental hygienist and were required to demonstrate their ability to floss all regions of the mouth, with additional instruction as needed. They were given written instructions and a supply of floss for once-daily home use. The article states that subjects were instructed "to continue their assigned regimen at home daily in addition to their usual oral hygiene procedures."⁸ Subjects were provided with toothpaste and toothbrushes as needed. (Id.).

The at-home use, which continued for six months, was unsupervised. Subjects were instructed to maintain diaries recording their compliance; rinsers were to initial twice a day when they rinsed and flossers were to initial once a day when they flossed. (See PX 57 at 352; PX 146). Subjects were to return to the clinical site once a month, bringing with them the unused rinse and floss, which were to be measured or weighed to check compliance. New supplies and diaries were to be issued for the next month. (PX 57 at 352). The subjects were re-instructed

⁸ The protocol for the study, however, states that subjects "will be instructed to refrain [from] using any other oral products other than the provided mouthrinse, toothpaste, toothbrush, or floss." (PX 29 at 10096219). Dr. Lori Kumar, the vice president of oral care research and development at Pfizer, testified at her deposition that she believed the statement in the article was a "mistake." (Kumar Dep. 120).

in their assigned regimens, as necessary. At three and six months, the subjects were examined and scored again, using the same indices for plaque and gingivitis. (PX 57 at 352). At the conclusion of the six months, 301 of the 319 subjects were deemed evaluable. (PX 57 at 353).

The authors concluded that, for the Modified Gingival Index, both interproximally and whole mouth, both Listerine and flossing were significantly more effective than the control rinse at both three and six months. (PX 57 at 353). For the Quigley-Hein Plaque Index (Turesky modification), both interproximally and whole mouth, Listerine was significantly more effective than the control at both three and six months and flossing was significantly more effective than the control at three months but not at six months. Scores for the third index, the bleeding index, also showed that Listerine and flossing were significantly more effective than the control group at both three months and six months, but a low number of bleeding sites was noted. (Id. at 353). In general, the Listerine results were better than the floss results. (Id.).

The authors noted that their study "was designed to simulate actual conditions under which flossing instruction might be employed in dental practice." (PX 57 at 354). The results, according to the authors, "indicated" that Listerine was "at least as good as" flossing in reducing interproximal gingivitis and "significantly more effective" than flossing in reducing interproximal plaque over the six-month period. (Id.).

The authors recognized, however, a potential issue as to compliance. The plaque reductions in the flossing group "appeared to be somewhat lower than would be expected," and there was greater improvement at three months than at six months, suggesting "a deterioration of flossing technique with increased time following instruction." (Id.). As in real life, the subjects apparently flossed better immediately after they received instruction from a dental hygienist, but the quality of their flossing apparently diminished with the passage of time. The authors wrote:

It might be hypothesized that in the current study, subjects failed to consistently wrap the floss around the line angles of the teeth and this, coupled with scoring of the plaque index at six sites (including facial and lingual interproximal sites) per tooth, resulted in small percentage changes in mean plaque indices over time.

(Id.).

The authors concluded that the study provided "additional support for the use of the essential oil mouthrinse as an adjunct to mechanical oral hygiene regimens." (Id. at 355). They cautioned that "[p]rofessional recommendations to floss daily should continue to be reinforced." (Id.).

b. The Bauroth Study

The Bauroth Study resulted in an article entitled "The efficacy of an essential oil antiseptic mouthrinse vs. dental floss in controlling interproximal gingivitis," published in March 2003 in the Journal of the American Dental Association.

134 J. A.D.A. 359 (2003) (PX 56). The Bauroth study was essentially identical to the Sharma Study, except that the Listerine group used Cool Mint Listerine rather than original Listerine.

The Bauroth Study started with 362 subjects, randomly divided into the same three groups (Listerine, flossing, and control), and they followed the same regimens, respectively, as in the Sharma Study. (PX 360 at 360). In the end, 324 of the 362 subjects were evaluable. (Id. at 362). The results were consistent with the results of the Sharma Study, as the Bauroth authors concluded that Listerine was "at least as good as" dental floss in controlling interproximal gingivitis. (Id. at 364). As did the authors of the Sharma Study, however, the Bauroth authors gave a cautionary note:

[F]lossing was somewhat less effective in reducing interproximal plaque levels than might be expected. The reasons for this could not be determined from the design study. However, we might hypothesize that this could result from either behavioral or technical causes. It has been shown, for example, that flossing effectiveness decreases considerably in the absence of frequent reinforcement and instruction, and that the motivation to floss decreases as the time since the last dental visit increases. It also might be that in the current study, as time went by, the subjects failed to consistently wrap the floss around the line angles of the teeth. That would mean that the plaque that was visually accessible and scored in the interproximal areas from the line angle to the contact area was at higher levels in the floss group than in the antiseptic rinse group.

(Id.) (footnotes omitted).

The Bauroth authors concluded: "[W]e do not wish to suggest that the mouthrinse should be used instead of dental floss or any other interproximal cleaning device." (Id.).

Neither the Bauroth Study nor the Sharma Study purported to examine whether Listerine could replace floss (Kumar Dep. 10), and neither study examined the efficacy of Listerine with respect to severe gingivitis or periodontitis or tooth decay or the removal of food debris. (Id. 32). In addition, neither study considered the adjunctive effects of Listerine when used in addition to brushing and flossing. (See PXs 56, 57).

4. The ADA Approval for Professional Advertising

The ADA requires that all labeling and advertising bearing the ADA seal of acceptance be submitted to the ADA for review and approval prior to use. (See DX 10 at 15019; Tr. 585-86). Listerine carries the ADA seal. (PX 162). In March 2002, Pfizer asked the ADA Council on Scientific Affairs to approve advertising to professionals, based on the Sharma and Bauroth Studies, claiming that Listerine is "as effective as flossing" and "as essential as flossing." (DX 408 at 3034, 3051, 3052, 3054; Tr. at 585). Pfizer acknowledged to the ADA that "[w]e recognize that any comparison vs. flossing may send an unintended message to dental professionals that Listerine can replace flossing," and Pfizer assured the ADA that its advertising was "constructed" to "ensure that this does not happen." (Id. at 3034 (emphasis in original); see also Tr. at 584; PX 52 at 1655).

Some consultants to the ADA expressed concerns about

the Pfizer studies and the proposed professional advertising.

One consultant noted:

It was a self-fulfilling prophecy . . . that the floss group would not be significantly better in six months over the other (brush only) control given the inappropriate preparation and follow through in the floss group. Because of floss' historically poor compliance record, a replacement for flossing [for] the regimen of daily plaque removal would be most welcome. However, in order for a substitute product to be "as good as" or "better" than flossing it must be compared against the data of a subject group who demonstrates they can and are flossing effectively, which the subjects in the flossing groups [in the two Pfizer studies] were not[,] based on the evidence presented.

(PX 60 at 10003126). Another consultant, who observed that the studies "appear to be well-done and controlled," nonetheless expressed concern regarding the measurement of compliance in the floss group and cautioned that "there is danger in misinterpretation of all of the potential draft ads proposed by Pfizer." (Id. at 100003128-29). Another consultant questioned whether the flossing subjects used proper flossing technique and warned that most readers of the ads "are likely to conclude what is most obvious from these ads, namely that floss and Listerine Antiseptic Mouthrinse are equally effective at inhibiting plaque and gingivitis and are, therefore, interchangeable." (Id. at 100003131-32). The same consultant also wrote:

If consumers conclude that floss and the mouthrinse are interchangeable and embark on the long-term use of the mouthrinse as a substitute for mechanical interdental cleansing, there is a risk that the mouthrinse regimen may not be as effective in preventing the onset of periodontitis as

mechanical interdental hygiene. Furthermore, individuals who may already be affected by periodontitis may be worse off in the long run if the mouthrinse is substituted for mechanical interdental cleansing. Such subjects were intentionally excluded from these studies, but could be adversely affected by the existing ads.

(Id. at 100003133).

Yet another consultant opined that the claims in the ads:

should not be allowed because they are too broad. The claims imply that the mouthrinse is as effective as floss without specifying that the populations studied only had 'mild' or 'slight' gingivitis. Certainly the data do not support the claim that the mouthrinse is as effective as flossing in patients with moderate to severe gingivitis or periodontitis. Such populations were not studied.

(Id. at 100003135).

Pfizer responded to these criticisms in May 2002. (PXs 27, 60). In doing so, Pfizer assured the ADA:

We have [reinforced] and continue to reinforce that dentists should continue to encourage their patients to brush and floss in all professional materials including the current proposed advertisement ('when brushing and flossing are not enough'). Brushing and flossing remain the standard of plaque control and indispensable for both disease-free and periodontally affected individuals. Use of Listerine mouthrinse is not interchangeable with flossing.

(PX 27 at 100009904) (emphasis in original).

By letter dated June 6, 2002, the ADA approved Pfizer's professional advertisements, as follows:

[T]he Council [on Scientific Affairs of the ADA] determined that Listerine . . . has been

shown, in two 6-month clinical studies, to be as good as flossing at reducing interproximal plaque and gingivitis in subjects with mild to moderate gingivitis who brush twice a day with a fluoride dentifrice. . . .

The Council concurs with your request for the claim, "Now clinically proven as effective as flossing" for patients with mild to moderate gingivitis. Since study subjects with advanced gingivitis or periodontitis were not included in the studies, no claim can be made about such patients. The Council did not approve the claim, "Now proven equally essential as flossing," because it believes that "as essential as" implies that studies have shown that all consumers must both floss and rinse with Listerine.

(PX 40). The ADA also approved the claim "New clinical studies prove that the antimicrobial action of Listerine is as effective as flossing." (Id.). The claims were approved for use only with professionals "because of the potential to mislead consumers that they no longer need to floss." (Id.; see Kumar Dep. 186-87; Tr. 629-30). The ADA noted that Pfizer had agreed that it "does not wish to promote the message that consumers can stop daily flossing if they rinse twice a day with Listerine." (PX 40; see Lynch Dep. 36 (flossing "has a place in oral hygiene and it has a benefit"))).

The ADA reported on the Pfizer studies in its own website. The ADA wrote that "[w]hile some study results [referencing the Sharma and Bauroth Studies] indicate the use of a mouth rinse can be as effective as flossing for reducing plaque between the teeth," it continued to recommend "brushing twice a day and cleaning between the teeth with floss or interdental cleaners once each day." (PX 51). The ADA noted that the

authors of the studies concluded that "in patients with mild to moderate gingivitis (early gum disease), rinsing twice a day with the antiseptic mouth rinse was as effective as flossing for reducing plaque and gingivitis between the teeth." (Id.). The ADA noted that the authors had not studied how the mouth rinse compared to floss in reducing tooth decay or periodontitis. (Id.).⁹

5. The Professional Advertising Campaign

After the ADA approval, Pfizer began an advertising campaign directed at the professional dental community. (Tr. 588, 589-90). The campaign included as its "centerpiece" a journal ad and it also included other ads, direct mail, sales visits, and reprints of the two studies. (Tr. 589-90; PX 36 at 10012270).

One of the ads shows a bottle of Cool Mint Listerine balanced -- equally -- on a scale opposite a container of dental floss. (DX 198; see Tr. 716-17). The ad proclaims: "Now Clinically Proven As Effective as Floss Against Plaque and Gingivitis." (DX 198). It further states that "[n]ew clinical studies prove that the antimicrobial action of Listerine is as effective as flossing." It further proclaims: "Significant reductions in plaque buildup and clinically comparable reductions in gingivitis." (Id.). It urges dentists to "Recommend

⁹ One Pfizer representative found fault with the ADA's description of the studies: "While I don't mind much of what they say, their spinelessness is obvious when it comes to the claim." (PX 111).

Listerine." (Id.). In small print, it states: "When brushing and flossing are not enough." (Id.). A similar ad, also showing a Listerine bottle balanced on a scale against a floss container, disclaims in fine print near the bottom of the page: "Floss daily." (DX 199).

6. The ADA Approval for Consumer Advertising

In January 2004, Pfizer sought approval from the ADA to expand its "as effective as flossing" advertising campaign to consumers. (Tr. 590; PX 36). Pfizer emphasized in its submission that it had spent the prior eighteen months "educating dental professionals." (PX 36 at 10012270).¹⁰ Pfizer stated: "We have now reached the stage where professionals have been exposed to this evidence-based claim more than 8.4 million times and we believe it is time for us to be able to reach out directly to the consumer." (Id.). Again Pfizer sought to assure the ADA that:

¹⁰ A number of individual dentists and hygienists complained directly to Pfizer that consumers would get the wrong message. (See, e.g., PX 74 ("I was aghast to read your newsletter wherein you indicate that rinsing with 'Listerine is as effective as floss.' Rinsing with water will reduce interproximal plaque. But there is no substitute for flossing. . . . [M]alarkey like this can set back years of progress by the ethical dental profession in convincing patients that flossing is essential for their oral health." (emphasis in original)); PX 75 ("We as dental professionals understand that simply rinsing with an antimicrobial solution is not a replacement for daily flossing, as it cannot address the subgingival bacteria and debris, which normally build[] up over the course of daily eating. . . . The statements [Pfizer is] making may be true, in that Listerine kills bacteria, and may remove some plaque, however, these same statements are somewhat misleading to the layperson."); see also PXs 79, 80).

we are taking appropriate, responsible and ethical measures to convey an unambiguous, yet creative and provocative, message to consumers that Listerine is not a replacement for flossing and that it is an adjunct to their usual mechanical oral care routine, which should include flossing daily.

(Id. at 10012271-72; see Tr. 584 (Pfizer "reassured [professionals] that once we went to the consumers we would not communicate a substitution message."); PXs 44, 45, 46, 47, 48, 49, 50, 81; Schorr Dep. 90; Kumar Dep. 52 ("Pfizer has no intention of telling people to stop flossing. We never have. We never will.")). In its supporting materials, Pfizer acknowledged that "flossing performed correctly and regularly remains the standard for maintaining optimal interproximal gingival health," but it contended that "chemotherapeutic agents may also serve a useful role especially in those patients whose brushing and flossing are inadequate to prevent and control gingivitis." (PX 36 at 10012280).

On March 29, 2004, the ADA approved Pfizer's request to use the "as effective as flossing" claim in advertising to consumers. (PX 66). The ADA provided, however, that the following language had to be "clearly communicated" to consumers in any advertising:

Rinsing with Listerine is as effective as flossing in removing interproximal plaque and in reducing interproximal gingivitis in patients with mild to moderate gingivitis when they brush twice a day with a fluoride dentifrice.

(Id.). The ADA also instructed that "in all consumer promotional materials using the Listerine is 'as effective as flossing'

claim, Pfizer will need to inform consumers that they should floss daily." (Id.).

Pfizer was concerned with the "very technical" nature of the qualifying language (Tr. 598), and on April 27, 2004, it proposed alternative language that it contended was "comprehensible at the 9-10th grade level":

Listerine is clinically proven as effective as floss (at reducing plaque and gingivitis between teeth).

Ask your dentist.

Floss daily.

(PX 89; see Tr. 598-99).

The ADA responded on May 19, 2004, approving the following similar language:

"Rinsing with Listerine is as effective as floss at reducing plaque and gingivitis between teeth."

"Ask your dentist."

"Floss daily."

(DX 453; Tr. 599-600).

Thereafter, Pfizer submitted various pieces of proposed promotional materials to the ADA for approval, including versions of the Big Bang television commercial, and approval was eventually received for advertisements that were eventually used publicly. (See, e.g., DXs 415, 416, 418; Tr. 612-15, 620-21). The ADA acknowledged that Pfizer had "increased the emphasis on the importance of flossing." (PX 68 at 10048321). The ADA noted that the Council on Scientific Affairs and ADA members had

expressed reservation about the "Listerine is as effective as floss" campaign, and noted that the ADA's advertising committee was interested in receiving "any feedback" that Pfizer might receive from consumers on the Big Bang commercial. (Id.). Prior to the launch of the consumer campaign, the ADA expressed concern about "the concept" that "if consumers don't have the time to floss, they can use Listerine instead." (PX 123; see also PX 121). In another letter, the ADA wrote:

It is the [ADA Ad] Committee's opinion that [a proposed] commercial is sending a mixed message to consumers, and that they will believe that it won't be a problem if they don't have time to brush or floss because Listerine is just as effective.

As the Council on Scientific Affairs approved the product as an adjunct for brushing and flossing for patients who need extra help, it would not be possible for the Ad Committee to approve the concept of the commercial (if you don't have the time to floss, then use Listerine instead). Disclaimers or minor word changes do not alleviate the concerns the Committee has about the basic premise of the commercial.

(PX 122).

7. The Consumer Advertising Campaign

The consumer advertising campaign was launched in June 2004. (See Tr. 646). Prior to the launch, Pfizer sent a letter to 150,000 dental professionals -- "practically the whole universe of dental professionals" -- advising that Pfizer would be engaging in a consumer advertising campaign conveying a "new message to patients stating that 'Listerine is as effective as floss.'" (Tr. 646; PX 44). The letter advised dentists that:

"Rest assured, as with the professional campaign, we will promote responsibly and emphasize to patients that rinsing with Listerine cannot take the place of flossing." (PX 44; see also Kumar Dep. 26 (stating that Pfizer directs patients to floss and professionals to teach patients to floss because flossing "is extremely important to professionals"))).

The first version of the Big Bang television commercial began airing in June 2004. (Tr. 45; PXs 90, 93). The launch, however, generated immediate concern among dental professionals. Pfizer attended a convention of the American Dental Hygienists' Association in Dallas in late June 2004. Its representatives observed:

The hot topic of conversation was the new Listerine commercial. Many professionals voiced concern over the message conveyed. Approximately 85% of professionals said patients would "get the wrong idea" and stop flossing. Convention team members [from Pfizer] stressed that Listerine is not a replacement for flossing.

(PX 70 at 10013105).

Pfizer representatives also attended a convention of the Academy of General Dentists in Anaheim in early July 2004 and reported:

The new advertising campaign was the big concern at this convention. The [Pfizer] convention team figures that 75-85% of the Dental professionals that were detailed had a negative reaction to the advertising; they were and are concerned [that] Listerine is sending the wrong message to their patients by saying "Listerine is as effective as floss."

(PX 71 at 10013110; see also PXs 69, 72, 84 ("I'm growing tired

of talking to cranky hygienists."), 87, 109, 125; but see also PX 106 (Pfizer e-mail seeking to dispel "stories" that dentists were angry about Pfizer's campaign)).

By letter dated June 23, 2004, J&J objected to the Pfizer "as effective as floss" advertisements, including the Big Bang commercial. J&J wrote that it was concerned that the advertising contained "false and misleading claims" comparing rinsing to flossing. (PX 129; see also PXs 130, 131, 132).¹¹

In part because of the concerns raised by the dental community, Pfizer made changes to the advertisements, but Pfizer continued to send the message that Listerine was "as effective as floss." In the third version of the Big Bang, which continues to run, the commercial announces that "Listerine's as effective as floss at fighting plaque and gingivitis. Clinical studies prove it." (PX 95; see PX 92).¹² The commercial cautions that "[t]here's no replacement for flossing," but states that "if you don't floss like you should, you can get its plaque-fighting benefits by rinsing." (PX 95; see PX 92). The commercial goes on to repeat two more times the message that Listerine is "as effective as flossing against plaque and gingivitis." (PX 95; see PX 92).

The commercial also shows a narrow stream of blue

¹¹ PPC had become aware during the fall of 2002 of the ads used in the professional advertising campaign, but had not contacted Pfizer to object. (Tr. 306-07).

¹² The third version is substantially similar to the first and second versions of the commercials. (See PXs 90, 91, 92).

liquid flowing out of a Cool Mint Listerine bottle, then tracking a piece of dental floss being pulled from a white floss container, and then swirling around and between teeth -- bringing to mind an image of liquid floss. (PX 95). In a superscript that appears briefly on-screen, the commercial also tells viewers to "[a]sk your dental professional." (PX 95; see PX 92).

Pfizer also published print ads, including a freestanding circular with a manufacturer's discount coupon featuring a bottle of Cool Mint Listerine balanced equally on a scale opposite a floss container (similar to the image used in the professional campaign). (PX 96).¹³ The ad proclaims that Listerine "Is Clinically Proven To Be As Effective as Floss at Reducing Plaque & Gingivitis between the Teeth." (Id.). In small print near the bottom of the page, the ad states: "Floss Daily." (Id.). There is no instruction telling consumers to consult their dentists. (See id.).

Pfizer also used a hang tag and shoulder labels on its bottles of Listerine. (PXs 97, 98, 162; DX 432). The hang tag features the scale image and is similar to the print ad just described. (PX 97; see PX 96). The shoulder label has gone through three versions. (See Tr. 616-20). The first version

¹³ In an e-mail, a representative at Pfizer's public relations firm expressed concern to Pfizer that it could be sending a "toss the floss" message to consumers and noted specifically that "advertising that shows a bottle of Listerine on a scale opposite a package of floss leaves [the] impression" that Listerine is an alternative to floss, "[a]s does the sound bite: 'Listerine is as effective as floss.'" (PX 103 at 10056811). The record is unclear whether the scale image is still being used.

(which was red) stated: "Now Clinically Proven As Effective As Floss," with the words in much smaller print "Against Plaque and Gingivitis Between the Teeth." (PXs 98, 162). The second version (which is blue) reads the same as the first, with the addition in small print of the words: "Ask Your Dentist. Floss Daily." (PX 100). A third version (which is gold and red) is being or is about to be distributed and reads: "As Effective As Floss Against Plaque & Gingivitis Between Teeth," with the following words in smaller print: "Ask Your Dentist. Not a Replacement for Floss." (DX 432).

Pfizer has also featured the "as effective as flossing" claim on its website for Listerine. The first page of the website shows the Cool Mint Listerine bottle shaking, with the stream of blue liquid flowing out (as in the Big Bang commercial), and forming the words "Listerine Antiseptic is as effective as flossing," with a footnote to the words: "Against plaque and gingivitis between teeth. Use as directed. Ask your dentist. Not a replacement for floss." (PX 41). The first page also states:

It's clinically proven.

A quick easy rinse with Listerine Antiseptic, twice a day, is actually as effective as floss. Because Listerine Antiseptic gets between teeth to kill the germs that cause plaque and gingivitis. Ask your dentist. You'll find out that Listerine Antiseptic truly is the easy way to a healthy mouth.

(Id. at 090617; see also <http://www.listerine.com> ("Listerine Antiseptic is as effective as flossing") (visited Jan. 3, 2005)).

The website has an entire section entitled "Effective As Floss," spanning many pages. In a question-and-answer section, the website addresses frequently asked questions, including the following:

Question 3 Most people don't like to floss/don't make the time to floss. Isn't this new data telling people that they don't have to floss?

Answer No, flossing is essential in preventing gum disease because it helps remove food particles and plaque from between the teeth, areas where the toothbrush can't reach. However, optimal plaque control through brushing and flossing alone can sometimes be difficult to achieve. We believe that the results [of the two studies] suggest the importance of adding an antiseptic mouthwash to patients' daily oral healthcare

(PX 41 at 090636-37).¹⁴

In December 2004, Pfizer began running a fourth version of the Big Bang. It is substantially similar to the third version, with the exception that it makes reference to Pfizer's new Advanced Listerine. (See Letter to Court from Kaye Scholer, dated December 28, 2004 & Enc.).¹⁵

¹⁴ At the preliminary injunction hearing, the Pfizer marketing director for Listerine testified that the answer on its website to Question 3 "probably isn't 100% accurate anymore" because the research performed and opinions provided in the course of this litigation that the "link" between removing food particles and reducing gum disease "doesn't seem to be supported." (Tr. 623; see also Tr. 639-40; Kumar Dep. 24 (disagreeing with first sentence of response to question 3)).

¹⁵ The fourth version apparently began airing on December 17, 2004, the day the preliminary injunction hearing in this case concluded. During the hearing, the lawyers made no mention of the fourth version, apparently because they were unaware that there was going to be a fourth version. I learned of the fourth

8. The Surveys

In September and October 2004, at PPC's request, a consumer research firm, Bruno and Ridgway Research Associates, conducted three consumer surveys in connection with this case, in malls and shopping centers in ten different locations throughout the United States. (Tr. 30-33). The first was intended to determine the message that consumers took away from the Big Bang commercial. The second sought to determine the message that consumers took away from the first of the three shoulder labels. The third sought to measure the pre-existing beliefs of consumers regarding the use of Listerine and floss. (Tr. 32-33; see PX 158).

In the first survey, consumers were shown the third version of Big Bang twice and then asked a series of questions about the ideas that were communicated to them by the commercial. The survey found that 50% of the respondents took away the message that "you can replace floss with Listerine." (Tr. 33; see PX 158 at 0012 ("one half (50%) of consumers who viewed the Listerine commercial[] take away a message that Listerine can be

version only because my son saw it while watching television and brought it to my attention. (See Letter to Court from Kaye Scholer, dated December 29, 2004 & Encs.). The fourth version continues to run, and all three of my law clerks saw it broadcast during the weekend of January 1, 2005 at different times, including twice during the broadcast of the New York Giants-Dallas Cowboys football game. I re-open the record and receive the videotape and storyboard of the fourth version as Court Exhibits B and C, respectively. Pfizer counsel's December 28 and 29, 2004 letters are received as Court Exhibits D and E, respectively.

used instead of floss"))).¹⁶

In the second survey, eligible consumers were shown a Listerine bottle with the first (or red) version of the shoulder label. They were asked essentially the same questions as were asked in the first survey. Some 45% of the consumers took away the message that Listerine could be used instead of floss. (Tr. 32-33; see PX 158 at 0017 ("just under one-half (45%) of consumers take away a message from the bottle labeling that Listerine can be used instead of floss")). Essentially the same methodology was followed as was followed for the first survey. (Tr. 41-42, 43-44).

In the third survey, a control survey, consumers were asked their "pre-existing beliefs" regarding Listerine and floss; the intent was to determine the number of people who did not recall seeing the commercials but who still believed that Listerine could be used instead of floss. A minority of those surveyed did not recall seeing Big Bang, and of those 19% stated the opinion that Listerine could be used in place of floss. (Tr. 33, 44-45; PX 158 at 0022 ("Among the 209 consumers who could not recall seeing the commercial, only 19% hold the opinion that you can use Listerine instead of floss. This proportion is likely

¹⁶ The 50% figure was based on certain of the answers to open-ended question 4 (36%) and the answers to close-ended question 6 (30%), with duplicative answers eliminated so that respondents who gave a replacement message answer to both questions were not counted twice. (Tr. 38-40; PX 158 at 0013, 0015).

inflated because" the Big Bang commercial had been running for several months.)).

The surveyors then took the three surveys together, subtracted the 19% figure from the 50% and 45% figures, respectively, and concluded that 31% of those who saw the commercial and 26% of those who viewed the shoulder label took away a replacement message. (Tr. 33, 49-50; see PX 158 at 0024 ("[I]f we use the 19% to adjust the communication levels reported in these surveys for the potential influence of pre-conceived opinions, we are still left with a substantial proportion of consumers who clearly received the 'can replace floss' message from the Listerine commercial and its bottle label.")).

Pfizer commissioned its own survey, which was conducted by Dr. Seymour Lieberman and his company, the Epsilon Group Inc., in shopping malls in twelve markets throughout the United States in August 2004. (Tr. 502-09, 543; see PX 164). Dr. Lieberman sought to determine the impact that the Big Bang commercial (the second version) was likely to have on sales of floss. (Tr. 503). Dr. Lieberman concluded that the Big Bang had "no negative impact" on consumers' expectations with respect to the purchase or use of floss. (Tr. 504; see PX 164 at 12).

Dr. Lieberman also sought to determine whether the commercial "created the idea that Listerine provides all of the benefits of floss without reservation." (Tr. 503). He did so by showing half the respondents the Big Bang commercial and half another Pfizer commercial for Listerine called "Simple Solution."

(Tr. 504-13; PX 164). The respondents were then asked a series of questions, and the stated intent was to use Simple Solution as a control to determine the number of people who took a replacement message away from Big Bang. (Tr. 511-14). According to Dr. Lieberman, Simple Solution was "a perfect control" because it did not "either implicitly or explicitly [make] the claim that Listerine is as effective as floss." (Tr. 514).

The storyboard for Simple Solution shows that the announcer says:

Do you always floss between all 32 teeth?
You would if you had the time.

Good thing there's Listerine.

In just 30 seconds, Listerine kills germs to
fight plaque build-up in places you may have
missed with brushing and flossing

(PX 164 at App. A, Simple Solution Storyboard).

Dr. Lieberman concluded that for both Big Bang and Simple Solution, the percentage of respondents expecting to buy mouthwash increased significantly after seeing the respective commercial. (PX 164 at 12; see Tr. 518). Dr. Lieberman also found that for both commercials, there were significant increases -- 23% for Big Bang and 19% for Simple Solutions -- in the number of people who believed that Listerine provides all the benefits of flossing. (PX 164 at 13 & Table B-7). Dr. Lieberman contended that these numbers showed that Big Bang did not cause consumers to take away a replacement message because the difference between 23% and 19% was not significant. (Tr. 521; PX 164 at 13).

Dr. Lieberman also found that after they saw the commercials, 49% of those who saw Big Bang and 45% of those who saw Simple Solution believed that "Listerine provides all of the benefits of flossing." (PX 164 at Table B-7 (emphasis in original)).

Pfizer earlier commissioned, in the spring of 2004, Ipsos-ASI, an advertising research company, to conduct quantitative -- or large-scale -- market research into the message being conveyed by several proposed advertisements or commercials using the "clinically proven as effective as floss" claim. (PX 11; see Tr. 653-55). In response to an earlier version of Big Bang, 27% of the respondents took away the message that Listerine "can substitute brushing/flossing." (PX 11 at 0003935). Some 10% responded that they took away the message "[d]on't have to floss/no need to floss." (Id. at 000397).¹⁷

9. The Impact of the Ads

PPC's sales of string floss have been "relatively stable" from a few months prior to the launch of Pfizer's advertising campaign to the time of the preliminary injunction hearing. There were two "peaks" in sales, which were likely the result of "buy one, get one free" promotions. (Tr. 290-91; see Tr. 314-15).

¹⁷ Another market research company commissioned by Pfizer, Sabena, conducted research in March and April 2004 to consider the effectiveness of various proposed commercials, including an earlier version of Big Bang. Sabena concluded that "[t]he many individuals who don't like to floss are excited by the prospect of flossing less often." (PX 10 at 10013646).

PPC's sales of the RADF and Power Flosser are down. There was a drop in sales from the beginning of the year prior to the launch of Pfizer's advertising campaign, which is likely the result of introduction into the market of another power flosser by a competitor. Sales of PPC's Power Flosser had actually increased prior to June 2004. From the time Pfizer launched its advertising campaign, sales of both the RADF and the Power Flosser have taken a steep decline. (Tr. 291).

It is not surprising that sales of string floss have not dropped while sales of the RADF and Power Flosser have. The string floss category is comprised predominantly of "people who are more loyal flossers," who would be less likely to replace floss with Listerine. Consumers who use the RADF and Power Flosser, in contrast, are predominantly "folks who don't like to floss," who "would love to have a replacement for flossing." These consumers "would be more susceptible to a message like the Listerine advertising campaign." (Tr. 292).

The consumer advertising campaign launched in mid-June 2004, and by July 2004 some 68 million people had already seen the Big Bang. The Big Bang has continued to run since then and is running currently as well. Since the ads began running, sales of Listerine have increased by at least 10%. (Tr. 669).

B. Prior Proceedings

This action was filed on September 28, 2004. The complaint asserts claims of false advertising in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and unfair

competition in violation of state law. On October 1, 2004, PPC moved by order to show cause for a preliminary injunction and expedited discovery. On October 6, 2004, the parties consented to a scheduling order and agreed to a schedule for expedited discovery, including expert discovery, and the submission of proposed findings of fact and conclusions of law. The Court conducted an evidentiary hearing from December 13 to 17, 2004, at the conclusion of which the Court reserved decision.

DISCUSSION

A. Applicable Legal Standards

1. Preliminary Injunctions

A party seeking a preliminary injunction must show that (1) it is likely to suffer irreparable injury if relief is denied and (2) there is either (a) a likelihood of success on the merits or (b) sufficiently serious questions going to the merits to make them a fair ground for litigation, with a balance of hardships tipping decidedly in the movant's favor. Procter & Gamble Co. v. Chesebrough-Pond's Inc., 747 F.2d 114, 118 (2d Cir. 1984); SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co., No. 01 Civ. 2775 (DAB), 2001 U.S. Dist. LEXIS 7061, *17 (S.D.N.Y.), aff'd, No. 01-7709, 2001 U.S. App. LEXIS 21472 (2d Cir. 2001). A preliminary injunction is an "extraordinary remedy" that should not be routinely granted. JSG Trading Corp. v. Tray-Wrap, Inc., 917 F.2d 75, 80 (2d Cir. 1990).

2. The Lanham Act

a. Irreparable Harm

In a Lanham Act false advertisement case,¹⁸ the Second Circuit has held that irreparable harm will be presumed where the plaintiff demonstrates a likelihood of success in showing that a comparative advertisement that mentions plaintiff's product by name is literally false. Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 62 (2d Cir. 1992); see also McNeilab Inc. v. American Home Prods. Corp., 848 F.2d 34, 38 (2d Cir. 1988) (making a distinction between false comparative advertising claims and those involving "misleading, non-comparative commercials which touted the benefits of the product advertised but made no direct reference to any competitor's product").

When irreparable harm is not presumed but plaintiff's and defendant's products are in head-to-head competition in the relevant market, the Second Circuit does not require plaintiffs to show an actual loss of sales. See Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 316 (2d Cir. 1982), abrogated on other grounds by Fed. R. Civ. P. 52(a); Zeneca Inc. v. Eli Lilly & Co., No. 99 Civ. 1452 (JGK), 1999 U.S. Dist. LEXIS 10852, at *104 (S.D.N.Y. July 19, 1999). Section 43 of the Lanham Act requires "only proof providing a reasonable basis for the belief

¹⁸ The parties agree that PPC's state law claims are governed by the same legal principles that apply to the Lanham Act claims. (See PPC Am. Prop. Findings of Fact & Concls. of Law at 66 n.13; Pfizer Prop. Am. Findings of Fact & Concls. of Law at 96 n.20).

that the plaintiff is likely to be damaged as a result of the false advertising." Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d 186, 190 (2d Cir. 1980) ("The correct standard is whether it is likely that [defendant's] advertising has caused or will cause a loss of [plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [defendant's] ads actually resulted in some definite loss of sales."). Proof that sales of plaintiff's products would probably be harmed if defendant's advertising tended to mislead consumers in the manner alleged is sufficient to establish irreparable injury. Coca-Cola, 690 F.2d at 316-17.

Requiring "more than a plaintiff's mere subjective belief" that injury has occurred or is likely to occur, Johnson & Johnson, 631 F.2d at 189, the standard may be satisfied if the plaintiff demonstrates that the parties are competitors in a relevant market and shows "a logical causal connection between the alleged false advertising and [plaintiff's] own sales position." Id. at 190-91 (finding that plaintiff satisfied this requirement with specific evidence that consumers use plaintiff's product for specific purposes and defendant's ad campaign affects those markets, and that plaintiff supports its case with sales data, a consumer witness' testimony that she changed products based on defendant's false advertising, and survey evidence of consumer confusion). Furthermore, injunctive relief is not barred just because the possibility that the total pecuniary harm might be relatively slight. See id.

b. The Merits

Section 43(a) of the Lanham Act prohibits false advertising, providing that:

Any person who . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C § 1125(a). Under the plain language of § 43(a), any person who believes that he or she is or is likely to be damaged by the false or misleading representations may bring suit under the Lanham Act. See Societe de Hotels Meridien, S.A. v. LaSalle Hotel Operating Partnership, L.P., 380 F.3d 126, 130 (2d Cir. 2004) ("We have consistently held that where the defendant has drawn a direct comparison between its own product and that of the plaintiff, we are inclined, without much more, to find standing to bring Lanham Act claims.").

To prevail on a Lanham Act false advertising claim, a plaintiff must demonstrate the falsity of the challenged advertisement, by proving that it is either (1) literally false, as a factual matter; or (2) implicitly false, i.e., although literally true, still likely to mislead or confuse consumers. See Societe de Hotels Meridien, 380 F.3d at 132; L&F Prods. v. Procter & Gamble Co., 45 F.3d 709, 711 (2d Cir. 1995) (citing Johnson & Johnson*Merck Consumer Pharms. Co. v. SmithKline

Beecham Corp., 960 F.2d 294, 297 (2d Cir. 1992)); accord Castrol, 977 F.2d at 62; McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991).

The false or misleading statement must be material. S.C. Johnson & Son, Inc. v. Clorox Co., 241 F.3d 232, 238 (2d Cir. 2001); National Basketball Assoc. v. Motorola, Inc., 105 F.3d 841, 855 (2d Cir. 1997); see also 4 McCarthy on Trademarks & Unfair Competition § 27:35 (there must be "some showing that the defendant's misrepresentation was 'material' in the sense that it would have some effect on consumers' purchasing decisions"). In considering the issue of falsity, the court should "'consider the advertisement in its entirety and not . . . engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately.'" Avis Rent A Car Sys., Inc. v. Hertz Corp., 782 F.2d 381, 385 (2d Cir. 1986) (quoting FTC v. Sterling Drug, Inc., 317 F.2d 669, 674 (2d Cir. 1963)). "[T]ext must yield to context." Avis, 782 F.2d at 385. Finally, the "visual images in a commercial" must also be considered in assessing falsity. S.C. Johnson, 241 F.3d at 238.

When the challenged statement is literally or explicitly false, the court may grant relief "'without reference to the advertisement's impact on the buying public.'" McNeil-P.C.C., 938 F.2d at 1549 (quoting Coca-Cola, 690 F.2d at 317); see also Castrol, 977 F.2d at 62 (finding that plaintiff bears the burden of proving challenged advertising is literally false to a "likelihood of success" standard). When a plaintiff relies

upon the "impliedly false" theory, however, extrinsic evidence must confirm that the advertising is likely to mislead or confuse. L&F Prods., 45 F.3d at 711.

In proving an advertising claim literally false, a plaintiff bears a different burden depending on whether the advertisement purports to be based on test results. Hence, where a defendant's advertisement contends that "clinical tests" prove the superiority of its product (an "establishment claim"), the plaintiff need only prove that "the tests referred to . . . were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited." Castrol, 977 F.2d at 62-63 (citing Procter & Gamble, 747 F.2d at 119). On the other hand, where a superiority claim does not purport to rest on test results, the plaintiff may prove falsity "'only upon adducing evidence' that affirmatively show[s] [defendant's] claim . . . to be false." Castrol, 977 F.2d at 62-63 (quoting Procter & Gamble, 747 F.2d at 116); accord McNeil-P.C.C., 938 F.2d at 1549.

Where a plaintiff proceeds on a claim of implied falsehood, the plaintiff "must demonstrate, by extrinsic evidence, that the challenged commercials tend to mislead or confuse consumers." Johnson & Johnson*Merck, 960 F.2d at 298; accord L&F Prods., 45 F.3d at 711. As the Second Circuit has explained, the inquiry is: "what does the public perceive the message to be?" Johnson & Johnson*Merck, 960 F.2d at 299. The trial judge may not determine whether an advertisement is

deceptive "based solely upon his or her own intuitive reaction." Id. at 297. The trial judge must first determine "what message was actually conveyed to the viewing audience," and then it must determine the truth or falsity of the message. Id. at 298; accord Clorox Co. Puerto Rico v. Proctor & Gamble Commercial Co., 228 F.3d 24, 34 (1st Cir. 2000) (same).

Typically, an implied claim is proven through the use of a consumer survey that shows a substantial percentage of consumers are taking away the message that the plaintiff contends the advertising is conveying. Johnson & Johnson*Merck, 960 F.2d at 298 ("the success of a plaintiff's implied falsity claim usually turns on the persuasiveness of a consumer survey"); Cicle Francesco Moser, S.R.L. v. Cannondale USA, Inc., 12 F. Supp. 2d 320, 324 (S.D.N.Y. 1998) (same). Cases have held that 20% would constitute a substantial percentage of consumers. See Johnson & Johnson-Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., Inc., 19 F.3d 125, 134 n.14 (3d Cir. 1994) (citing cases finding "deception rates" of 20% or more to be sufficient). Survey results are useful and have "evidentiary value" if the surveys are properly designed and objectively and fairly conducted -- for example, they employ "filters" to screen out individuals whose responses may distort the results; the questions are directed to "the real issues"; and the questions are not leading or suggestive. Johnson & Johnson*Merck Consumer Pharms. Co. v. SmithKline Beecham Corp., 960 F.2d at 300;

Universal City Studios, Inc. v. Nintendo Co., 746 F.2d 112, 118 (2d Cir. 1984).

After a plaintiff has established that a substantial number of consumers have taken away the purported message, the district court must then evaluate whether the message is false or likely to mislead or confuse, and may consider factors such as the commercial context, the defendant's prior advertising history, and the sophistication of the advertising audience. See Johnson & Johnson*Merck, 960 F.2d at 298. Of course, the court must also consider the text and images used in the advertisement and the evidence offered to prove or disprove the truth of the asserted claim.

The plaintiff need not rely on consumer survey evidence to prove an implied falsity claim if the plaintiff "'adequately demonstrates that a defendant has intentionally set out to deceive the public,' and the defendant's 'deliberate conduct' in this regard is of an 'egregious nature.'" Johnson & Johnson*Merck, 960 F.2d at 298-99 (quoting Resource Developers, Inc. v. Statue of Liberty-Ellis Island Found., Inc., 926 F.2d 134, 140 (2d Cir. 1991)). In these circumstances, "a presumption arises 'that consumers are, in fact, being deceived.'" Johnson & Johnson*Merck, 960 F.2d at 298-99 (quoting Resource Developers, 926 F.2d at 140).

B. Application

I discuss first the issue of irreparable harm and second the merits.

1. Irreparable Harm

I conclude that PPC has demonstrated that it is likely to suffer irreparable harm if a preliminary injunction is not granted. First, as I conclude below, PPC has demonstrated a likelihood of success on its claim that Pfizer's ads are literally false. Pfizer's ads are comparative ads, and although they do not specifically mention PPC's product by name, PPC is the market leader in sales of floss, with 40% or more of the string floss category. (Tr. 286). As a PPC marketing executive testified: "[PPC's] brand really is the floss category to many consumers." (Tr. 293). In addition, the Pfizer ads feature a white floss container similar to if not identical to J&J's white floss container. (See, e.g., PX 92, 96, 97). Accordingly, irreparable harm is presumed. See Castrol, 977 F.2d at 62.

Second, even assuming the presumption is inapplicable, in the context of this case, where Pfizer is directly comparing Listerine to floss, Pfizer and PPC are in head-to-head competition for the same market -- non-flossers or reluctant flossers. These individuals would be easily enticed by the notion that they could obtain the benefits of flossing by rinsing with Listerine. Moreover, there may very well be a future impact on regular flossers as well. Hence, PPC is not required to show actual loss of sales; it can prove irreparable harm by showing "a logical causal connection between the alleged false advertising and its own sales position." Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d at 190. Such a logical causal connection

has been shown. In fact, by July 2004, when Pfizer's advertising campaign was just a few weeks old, some 68 million people had already seen Big Bang. Under all the circumstances, I conclude that it is likely that Pfizer's ads will adversely affect PPC's sales, if they have not done so already.

Third, it is likely that the ads already have adversely affected PPC's sales. Although PPC's string floss sales have remained stable, its sales of the RADF and Power Flosser -- which employ pieces of string floss -- have sharply declined since Pfizer launched its advertising campaign. It is here that PPC will most readily be hurt, for it is the consumers who do not floss or rarely floss who are more likely to replace floss if they are persuaded they can obtain the same benefits by rinsing with Listerine. Significantly, sales of Listerine have increased at least 10% since Pfizer started its "as effective as floss" campaign.

Accordingly, I conclude that PPC has met the first prong of the test for a preliminary injunction.

2. The Merits

I conclude that PPC has demonstrated a likelihood of success on both its literal falsity claim and on its implied falsity claim. I address each claim in turn.

a. Literal Falsity

Pfizer's advertisements make the explicit claim that "clinical studies prove that Listerine is as effective as floss against plaque and gingivitis." As Pfizer purports to rely on

"clinical studies," this is an "establishment claim" and PPC need only prove that "the [studies] referred to . . . were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited." Castrol, 977 F.2d at 62-63. Two questions are presented: first, whether the Sharma and Bauroth Studies stand for the proposition that "Listerine is as effective as floss against plaque and gingivitis"; and second, assuming they do, whether the studies are sufficiently reliable to permit one to draw that conclusion with "reasonable certainty."

First, even putting aside the issue of their reliability, the two studies do not stand for the proposition that "Listerine is as effective as floss against plaque and gingivitis." The two studies included in their samples only individuals with mild to moderate gingivitis. They excluded individuals with severe gingivitis or with any degree of periodontitis, and they did not purport to draw any conclusions with respect to these individuals. Hence, the literal claim in Pfizer's advertisements is overly broad, for the studies did not purport to prove that Listerine is as effective as floss "against plaque and gingivitis," but only against plaque and gingivitis in individuals with mild to moderate gingivitis. The advertisements do not specify that the "as effective as floss" claim is limited to individuals with mild to moderate gingivitis. Consequently, consumers who suffer from severe gingivitis or periodontitis (including mild periodontitis) may be misled by the ads into

believing that Listerine is just as effective as floss in helping them fight plaque and gingivitis, when the studies simply do not stand for that proposition.

Second, the two studies were not sufficiently reliable to permit one to conclude with reasonable certainty that Listerine is as effective as floss in fighting plaque and gingivitis, even in individuals with mild to moderate gingivitis. What the two studies showed was that Listerine is as effective as floss when flossing is not done properly. The authors of both studies recognized that the plaque reductions in the flossing groups were lower than would be expected and hypothesized that "behavioral or technical causes" were the reason. (PX 56 at 364; see also PX 57 at 354). Significantly, in some of the plaque reduction scores for the flossing groups there was greater improvement at three months than at six months, suggesting a deterioration in flossing technique with the passage of time. (PX 57 at 354).¹⁹

¹⁹ As Pfizer's expert, Dr. Raul Garcia, acknowledged, in a clinical study it is important to be able to evaluate compliance. (Tr. 452). He acknowledged that one cannot conclude that a clinical trial proves that Listerine is "as effective as floss" without ensuring that the subjects complied. (Tr. 456-57). Although he testified at the hearing that in his opinion there was "[a]bsolutely substantial compliance" (Tr. 428), he conceded on cross-examination that he had written in his report that in the two studies "it cannot be determined how well subjects performed their assigned flossing." (Tr. 452). The fact is that the authors in both studies recognized that a substantial question existed with respect to compliance.

The daily regimens were unsupervised, and compliance was measured simply by subjects initialing a diary and returning the unused Listerine and floss on a monthly basis. The flossing subjects were given instructions on flossing (orally and in

Hence, the studies did not "prove" that Listerine is "as effective as floss." Rather, they proved only that Listerine is "as effective as improperly-used floss." The studies showed only that Listerine is as effective as floss when the flossing is not performed properly. As one of the ADA consultants observed in objecting to the advertising when it was proposed, "for a substitute product to be 'as good as' or 'better' than flossing it must be compared against the data of . . . subject[s] who demonstrate they can and are flossing effectively." (PX 60 at 100003126; see also Tr. 182-83).

Pfizer and its experts argue that the two studies are reliable, notwithstanding the indications that the participants in the flossing group did not floss properly, because these conditions reflect "real-world settings." (Tr. 439; see Tr. 441, 459-60). But the ads do not say that "in the real world," where most people floss rarely or not at all and even those who do floss have difficulty flossing properly, Listerine is "as effective as floss." Rather, the ads make the blanket assertion

writing) at the outset, and no further instruction was given unless a subject requested it at one of the monthly visits. Nothing more was done to ensure that the subjects were flossing properly. (See Tr. 169). Subjects were included in the trial who had rarely or never flossed before. (Tr. 170). In addition, in the design of the studies, a compliance figure (80% of the prescribed amount) was set for Listerine but no compliance figure was set for flossing. (Tr. 172-75, 177, 429-32, 455). Some individuals were indeed excluded from the Sharma Study for failing to meet the 80% compliance figure. (Tr. 430). At some point a standard was set for floss compliance, and some of the floss subjects apparently used as little as 50 or 55 or 60% of the floss they were expected to use, and yet they were not excluded from the analysis. (Tr. 176-77, 455-56).

that Listerine works just as well as floss, an assertion the two studies simply do not prove. Although it is important to determine how a product works in the real world, it is probably more important to first determine how a product will work when it is used properly.

Not surprisingly, Pfizer relies heavily on the ADA's approval of its "as effective as floss" campaign as well as the ads themselves. Although this is a significant fact, the ADA's approval is not controlling. First, it is clear that the ADA's endorsement was hardly unanimous. Second, the ADA itself repeatedly emphasized to Pfizer that consumers were not to be misled into believing "they no longer need to floss." (PX 40). Third, the ADA also noted that the studies did not address individuals with severe gingivitis or periodontitis or consider the impact on tooth decay. (Id.; PX 51). Finally, based on the extensive record presented on this motion, I believe the ADA was simply wrong in approving the message that "clinical studies prove" that Listerine is as effective as floss in fighting plaque and gingivitis.

Accordingly, I hold that PPC is likely to succeed on its claim of literal false advertisement.

b. Implied Falsity

In considering the claim of implied falsity, in accordance with Second Circuit law, I determine first the message that consumers take away from the advertisements and second whether that message is false.

(i) The Implicit Message

Pfizer argues that its advertisements do not implicitly send the message that Listerine is a replacement for floss. I disagree. Rather, I find that Pfizer's advertisements do send the message, implicitly, that Listerine is a replacement for floss -- that the benefits of flossing may be obtained by rinsing with Listerine, and that, in particular, those consumers who do not have the time or desire to floss can switch to Listerine instead.

First, the words and images used in the advertisements confirm that this is the message being sent. The words ("as effective as floss") and images (a stream of blue liquid tracking floss as it is removed from a floss container and then swirling between and around teeth; a bottle of Listerine balanced equally on a scale against a container of floss) convey the impression that Listerine is the equal to floss.

Second, the Ridgway survey is convincing and was conducted in a generally objective and fair manner. I accept its findings as well as the testimony of Mr. Ridgway. Pfizer's objections to his conclusions are rejected.²⁰ The Ridgway

²⁰ For example, Pfizer's expert, Dr. Lieberman, objected to Mr. Ridgway's coding of the responses to the open-ended question 4. Survey respondents gave varying answers in their own words; some of the answers related to the effectiveness of Listerine as compared to floss and some of the answers related to whether Listerine could be used as a replacement for floss. Mr. Ridgway coded the answers and found that 50% of the respondents gave answers falling into the first category and 36% gave answers falling into the second category. (See PX 158 at 0013; Tr. 35, 38-39). The objections to the coding of the answers that fell

surveys show that 31% and 26% of the consumers who saw Big Bang and the shoulder label, respectively, took away the message that "you can replace floss with Listerine." (Tr. 33). Hence, a substantial percentage of the consumers who saw the advertisements took away a replacement message.

Third, even Pfizer's survey expert, Dr. Lieberman, made findings corroborating Mr. Ridgway's conclusions. Dr. Lieberman found that 49% of those who saw Big Bang believed "Listerine provides all of the benefits of flossing." (PX 164 at Table B-7 (emphasis in original)).²¹ Even Dr. Lieberman's results, then,

into the first category, however, are not terribly relevant because the answers were not included in the total of 50% Mr. Ridgway concluded had taken away a replacement message from the commercial. (Tr. 138-39, 527-28). Dr. Lieberman also objected to the inclusion into the second category of responses to the effect that the respondent had taken away from the commercial only a "qualified" replacement message; this objection is meritless, for even a "qualified" replacement message is still a replacement message. (See Tr. 528-30). The ADA was specifically troubled, for example, by the possibility that a message would be sent that "if consumers don't have the time to floss, they can use Listerine instead." (PX 123). Likewise, I believe Mr. Ridgway properly included answers to the effect that "you should use Listerine instead of floss" when Dr. Lieberman would have excluded such answers. (Tr. 529-30 (emphasis added)).

²¹ To the extent Dr. Lieberman opined that his test results showed that Big Bang did not convey a replacement message, his testimony is rejected. First, Simple Solution was not a good control, for, in my view, it implied that Listerine is a good substitute if one does not have time to floss, a similar message to that sent by Big Bang. (See Tr. 515-16). Second, Dr. Lieberman did not ask consumers what message they believed the commercials were conveying; instead, he asked them what their beliefs were -- "Which one of these statements do you believe applies to Listerine mouthwash?", with the possible answers being it provides "all," "some," or "none" of the benefits of flossing. (PX 164 at App. C, p. 8 (question 14); see Tr. 553-56). There is an obvious difference between the message a consumer understands a commercial to be sending and whether the consumer believes it to be true. Third, the survey was poorly designed. Consumers

show that a substantial percentage of consumers took away a replacement message.

Fourth, Pfizer's own documents, including the Ipsos study, the Sabena report, internal reports of feedback from the dental community (including the overwhelming reactions at the two dental conventions), and internal documents showing that Pfizer anticipated and prepared responses to deal with complaints that it was sending a message that consumers could rinse instead of floss, further confirm that consumers were and are taking away a replacement message. (See, e.g., PXs 10, 11, 27, 36, 69, 70, 72, 84, 87, 109, 125).

Pfizer argues that the ads contained cautionary language and disclaimers telling consumers to "floss daily," urging them to consult their dentists, and noting that "[t]here's no replacement for flossing." Hence, Pfizer argues, its ads are not conveying a replacement message. The argument is rejected. Notwithstanding the disclaimer language, Pfizer's ads are clearly suggesting to consumers, through its overall words and images, that if they do not have the time or desire to floss, they can

were asked questions about Listerine and flossing (and whether Listerine provides any of the benefits of flossing) before they were shown the commercial and then they were asked the questions again. Hence, although Dr. Lieberman acknowledged that it was important not to "clue" respondents in on the subject matter of the test before showing them a commercial, here the consumers were given an idea of what to look for in the commercials before they saw them. (See Tr. 557-59). Fourth, some version of Big Bang had been running for some two or three months when Dr. Lieberman conducted his survey, and no "filter" question was asked to screen out consumers who might have been tainted because they had already seen the commercial. (Tr. 540-44, 561).

rinse with Listerine instead, for Listerine is just "as effective as floss." The few words of disclaimer are lost when the ads are considered as a whole. After all, the point of an implied falsity claim is that even though an advertisement "is literally true it is nevertheless likely to mislead or confuse consumers." Johnson & Johnson*Merck, 960 F.2d at 297.²²

Finally, Pfizer relies heavily on the Seventh Circuit's decision in Mead Johnson & Co. v. Abbott Lab., 201 F.3d 883 (7th Cir. 2000). There, Judge Easterbrook wrote that:

interpreting "misleading" [in § 43(a)(1) of the Lanham Act] to include factual propositions that are susceptible to misunderstanding would make consumers as a whole worse off by suppressing truthful statements that will help many of them find superior products. A "misunderstood" statement is not the same as one designed to mislead.

201 F.3d at 886. The Mead Johnson decision, however, is of little assistance in this case. The issue there was whether the statement "1st Choice of Doctors" on infant formula containers was misleading and constituted false advertisement. The plaintiff argued that "1st" meant more than 50% and that a simple plurality would not suffice. Understandably, the Seventh Circuit rejected the argument. Here, the advertised claim is much less nebulous -- it is a claim based on purported proof provided by "clinical tests." Moreover, the court in Mead Johnson was

²² Moreover, when consumers see the words "as effective as floss in fighting plaque and gingivitis," they are not likely to appreciate the distinction between "plaque and gingivitis" and "tooth decay and periodontitis." (See PX 88 at 16914).

concerned that surveys were being used in that case "to determine the meaning of words." Id. at 886. The court observed that "[i]t would be a bad idea to replace the work of these professionals [philologists and others who contribute to dictionaries] with the first impressions of people on the street." Id. In this case, the Ridgway surveys were used in the manner in which surveys are traditionally used in false advertisement cases. The Mead Johnson decision does not dictate a different result here.

Accordingly, I conclude that the Pfizer ads send an implicit message that Listerine is a replacement for floss.

(ii) **Falsity**

The final inquiry, then, is whether the implicit message sent by the Pfizer ads is false. Pfizer argues that even assuming the advertisements do send a replacement message, the message is true: Listerine provides all the benefits of flossing.

Pfizer's position is based on two premises. First, Pfizer contends, the Sharma and Bauroth Studies prove that Listerine is as effective as floss in fighting plaque and gingivitis. Second, Pfizer contends, no clinical proof exists to show that flossing provides any benefit other than fighting plaque and gingivitis -- there is no clinical proof that flossing reduces tooth decay or periodontitis. Indeed, Pfizer asserts, this notion is a "myth," and goes so far as to argue that there is no proof that reducing plaque will reduce caries or

periodontitis. (See, e.g., Tr. 349-51 (Pfizer's expert, Dr. Hujoel, arguing that there is no connection between plaque and periodontitis)). Hence, Pfizer continues, because Listerine does everything that floss can do, Listerine therefore provides all the benefits of floss -- and consumers can "toss the floss" and replace it with Listerine.

These arguments are rejected. I conclude that the implicit message sent by Pfizer's advertisements is false, for Listerine is not a replacement for floss.

First, as discussed above, Pfizer's initial premise is wrong. The Sharma and Bauroth Studies do not prove that Listerine is just as effective as floss in fighting plaque and gingivitis. They prove only that Listerine is just as effective in fighting plaque and gingivitis as improperly-used floss. One simply cannot conclude from the two studies that Listerine is just as effective as flossing when the flossing is performed properly.

Second, Pfizer's second premise is wrong as well: there is substantial, convincing clinical, medical, and other proof to show that flossing does fight tooth decay and periodontitis and that Listerine is not a replacement for flossing.

Flossing provides certain benefits that Listerine does not. Floss penetrates subgingivally to remove plaque and biofilm below the gumline. Flossing, as part of a regular oral prevention program, also can reduce periodontitis. Flossing also

reduces tooth decay and has an anti-caries effect. Finally, flossing removes food debris interdentally, including pieces of food trapped between the teeth that rinsing cannot dislodge. (See generally Tr. 151-67 (testimony of Dr. Paquette); PX 51 (ADA website)).

Numerous articles confirm that tooth decay and periodontitis can be reduced or prevented through interdental plaque control methods, including flossing. (See, e.g., articles cited in footnotes 2 and 3 supra). One study in particular -- the Dorchester study -- is instructive in this respect. (PX 215 (G.Z. Wright et al., "The Dorchester Dental Flossing Study: Final Report," 1 Clinical Preventive Dentistry 23 (1979))). This was a 20-month clinical trial conducted with children to determine whether flossing -- done regularly and properly -- had any effect on the incidence of new caries. (Id. at 26). This was a "split-mouth" study: each child had one side of his or her mouth flossed each school day by a dental assistant; the other half of the mouth was not flossed. (Id. at 23). Hence, the design provided for both test and control surfaces in the same mouth and there was no issue about compliance. In the end, there was a striking difference -- there was more than a 50% reduction in the number of new caries on the flossed side relative to the unflossed side. (Id. at 24, 26; see generally Tr. 161-62).

As Pfizer's experts pointed out, there were some limitations to the Dorchester study. The sample size was small (only 88 children); the study was conducted many years ago (in

the mid-1970's); the study was conducted only with children (no adults were included); the study was conducted in a "fluoride-deficient town" in Ontario, Canada; and the study does not reflect real-world conditions, as the flossing was performed by dental assistants on almost a daily basis. (PX 23, 26). Nonetheless, the study demonstrates the benefits of flossing when flossing is performed properly, and those benefits include reducing the incidence of caries. Moreover, the Dorchester study is corroborated by other studies. (See, e.g., PXs 210, 211, and other articles cited in footnotes 2 and 3 supra). Again, although real-world usage is important, it is also important to study the efficacy of a product when it is used correctly.

Other substantial evidence also demonstrates, overwhelmingly, that flossing is important in reducing tooth decay and periodontitis and that it cannot be replaced by rinsing with a mouthwash. The ADA continues to say on its website that "[p]laque is responsible for both tooth decay and gum disease." (PX 51). Even in discussing the two Pfizer Listerine studies, the ADA continued to proclaim to consumers: "FLOSSING RECOMMENDED FOR GOOD ORAL HEALTH CARE." (Id. see also PXs 40, 66, 68, 122)). In the very articles upon which Pfizer based its advertising campaign, the authors emphasized that dental professionals should continue to recommend daily flossing and cautioned that they were not suggesting that mouthrinse be used instead of floss. (PX 57 at 354; PX 56 at 364). Pfizer itself continues to recognize on its own website that "flossing is

essential in preventing gum disease." (PX 41 at 090636). It also repeatedly acknowledged to the ADA that Listerine was "not interchangeable with flossing" (PX 27 at 100009904) and it repeatedly reassured both the ADA and the professional dental community that it was not intending to send a replacement message. (See, e.g., PXs 27, 36, 44-50, 70, 81). Yet, after telling the ADA and dental professionals for two years that it was not suggesting that floss can be replaced by Listerine, it takes that position in this lawsuit. Pfizer's complete turn-around is highly troubling.²³

Finally, of course, dentists and hygienists have been telling their patients for decades to floss daily. They have been doing so for good reason. The benefits of flossing are real -- they are not a "myth." Pfizer's implicit message that Listerine can replace floss is false and misleading.

CONCLUSION

In sum, I find that PPC has demonstrated that it will suffer irreparable harm if a preliminary injunction is not issued, and I find further that PPC has demonstrated a likelihood of success on both its literal falsity claim and on its implied falsity claim. In addition, although I do not reach the "serious

²³ Remarkably, in an effort to persuade the Court that common sense is inapplicable -- I asked whether, as a matter of "common sense" removal of plaque would reduce tooth decay -- Pfizer's expert, Dr. Hujoel, testified that the application of common sense, or "biological plausibility" as he called it, could lead to dangerous results, and used "blood letting" as an example. (See Tr. 352-54, 367-69, 370-72).

issues" prong of the test for a preliminary injunction and therefore am not required to weigh the equities, I find that the equities tip decidedly in favor of PPC. In addition, I find that Pfizer's false and misleading advertising also poses a public health risk, as the advertisements present a danger of undermining the efforts of dental professionals -- and the ADA -- to convince consumers to floss on a daily basis.²⁴

PPC's motion for a preliminary injunction is granted to the extent that I will issue an order enjoining Pfizer, during the pendency of this lawsuit, from communicating, in its advertising or promotional materials or activities, the claims that: (1) clinical studies prove that Listerine is as effective as floss (in any respects), provides the same benefits as floss, or can replace floss; (2) Listerine is as effective as, or can be used instead of, floss; (3) flossing provides no health benefits beyond reducing plaque and gingivitis; and (4) the Sharma and Bauroth Studies prove anything concerning the comparative oral health benefits of Listerine versus flossing. Pfizer is not enjoined from using the Sharma and Bauroth Studies to support the claim that Listerine fights plaque and gingivitis, as long as it does not invoke a comparison to floss.

PPC's request for an order directing Pfizer to engage in corrective advertising is denied, without prejudice to renewal following a trial on the merits.

²⁴ I have considered Pfizer's laches defense. It is rejected.

The parties shall promptly discuss the issues of (i) PPC's request for a recall of Listerine bottles that feature a hang tag or shoulder label containing the "as effective as floss" claim; (ii) the amount of a bond pursuant to Fed. R. Civ. P. 65(c); and (iii) the language of a proposed order. I note that PPC submitted a proposed order with its proposed findings of fact and conclusions of law.

As for a stay pending appeal, I am not inclined to grant a stay pending appeal, but I would consider a brief stay to permit Pfizer to seek immediate relief from the Second Circuit.

Counsel for the parties shall appear for a conference on January 10, 2005, at 2 p.m. In the meantime, the preliminary injunction is not yet in effect.

SO ORDERED.

Dated: New York, New York
January 6, 2005



DENNY CHIN
United States District Judge

APPEARANCES

For Plaintiff:

KRAMER LEVIN NAFTALIS & FRANKEL LLP
By: Harold P. Weinberger, Esq.
Jeffrey W. Davis, Esq.
Marjorie E. Sheldon, Esq.
Jennifer L. Rochon, Esq.
919 Third Avenue
New York, NY 10022

For Defendant:

KAYE SCHOLER LLP
By: Fredric W. Yerman, Esq.
Thomas A. Smart, Esq.
Aaron Stiefel, Esq.
Richard A. De Sevo, Esq.
Janeen F. Berkowitz, Esq.
425 Park Avenue
New York, NY 10022-3598